

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1938-LPS
v.)	
)	
ZENARA PHARMA PRIVATE LTD. And)	
BIOPHORE INDIA PHARMACEUTICALS)	
PRIVATE LTD.,)	
)	
Defendants.)	
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OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1939-LPS
v.)	
)	
AJANTA PHARMA LTD.,)	
)	
Defendant.)	
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OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1952-LPS
v.)	
)	
AMNEAL PHARMACEUTICALS LLC,)	
AMNEAL PHARMACEUTICALS)	
COMPANY GMBH, and RAKS PHARMA)	
PVT. LTD.,)	
)	
Defendants.)	
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OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1954-LPS
v.)	
)	
HETERO LABS LTD., HETERO LABS LTD.)	
UNIT-V, HETERO USA, INC., HETERO)	
DRUGS LTD., and HONOUR LAB LTD.,)	
)	
Defendants.)	
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OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1955-LPS
v.)	
)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendant.)	
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OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1956-LPS
v.)	
)	
PRINSTON PHARMACEUTICAL INC.,)	
)	
Defendant.)	
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OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1964-LPS
v.)	
)	
ALKEM LABORATORIES LTD.,)	
)	
Defendant.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1965-LPS
v.)	
)	
AUROBINDO PHARMA LTD. and)	
AUROBINDO PHARMA USA, INC.,)	
)	
Defendants.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1977-LPS
v.)	
)	
UNICHEM LABORATORIES LTD.,)	
)	
Defendant.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1987-LPS
v.)	
)	
ACCORD HEALTHCARE INC.,)	
)	
Defendant.)	
)	

OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-1988-LPS
v.)	
)	
LUPIN LIMITED AND LUPIN)	
PHARMACEUTICALS, INC.,)	
)	
Defendants.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-2006-LPS
v.)	
)	
APOTEX INC., APOTEX CORP., APOTEX)	
PHARMACHEM INC., and SIGNA S.A. DE)	
C.V.,)	
)	
Defendants.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-2007-LPS
v.)	
)	
ALEMBIC PHARMACEUTICALS LTD. and)	
ALEMBIC PHARMACEUTICALS, INC.,)	
)	
Defendants.)	
)	

OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-2008-LPS
v.)	
)	
OPTIMUS PHARMA PVT. LTD.,)	
)	
Defendant.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
and H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-2009-LPS
v.)	
)	
MSN LABORATORIES PVT. LTD., MSN)	
PHARMACEUTICALS INC., and MSN LIFE)	
SCIENCES PVT. LTD.,)	
)	
Defendants.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
AND H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-2024-LPS
v.)	
)	
ZYDUS PHARMACEUTICALS (USA) INC.)	
AND CADILA HEALTHCARE LTD.,)	
)	
Defendants.)	
)	
)	

OTSUKA PHARMACEUTICAL CO., LTD.)	
AND H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-2065-LPS
v.)	
)	
MACLEODS PHARMACEUTICALS LTD.)	
and MACLEODS PHARMA USA, INC.,)	
)	
Defendants.)	
)	
OTSUKA PHARMACEUTICAL CO., LTD.)	
AND H. LUNDBECK A/S,)	
)	
Plaintiffs,)	
)	C.A. No. 19-2080-LPS
v.)	
)	
SANDOZ INC. and SANDOZ)	
INTERNATIONAL GMBH,)	
)	
Defendants.)	
)	

JOINT STATUS REPORT

Pursuant to the Court’s September 14, 2020 Order (D.I. 25 in C.A. No. 19-1938-LPS), the parties submit this joint status report as to how they believe these cases should proceed.

This is an action for patent infringement of Otsuka Pharmaceutical Co., Ltd.’s patents covering REXULTI® (brexpiprazole), an antipsychotic drug for the treatment of schizophrenia and major depressive disorder. Defendants in these actions have submitted Abbreviated New Drug Applications (“ANDAs”) seeking U.S. Food and Drug Administration (“FDA”) approval for their generic brexpiprazole products giving rise to Plaintiffs’ allegations of patent infringement. Plaintiffs have asserted five patents-in-suit: U.S. Patent Nos. 7,888,362; 8,349,840; 8,618,109; 9,839,637 and 10,307,419 (“the ’419 patent”), which cover brexpiprazole, its use and pharmaceutical formulations.

In addition to discussing the Rule 12(c) issues pertaining to the '419 patent, the parties have largely agreed to a schedule and to consolidation of these actions into lead action C.A. No. 19-1938-LPS. The Proposed Scheduling Order is attached as Exhibit 1 hereto. In the hope that it will be helpful, the parties set forth their positions concerning the remaining disputes regarding the Scheduling Order in Section III below.

I. Rule 12(c)-Related Motions

PLAINTIFFS' POSITION:

The Rule 12(c) motions of Optimus, Princeton and Hetero and the motion for leave to file a Rule 12(c) motion of Zenara should all be dismissed or disallowed for common reasons: (1) they are not *case* dispositive and will not significantly streamline these actions; and (2) they impermissibly rely on matters outside the pleadings—their ANDAs and the prosecution file histories of the '419 patent and its parent applications (*e.g., Par Pharm., Inc. v. Hospira, Inc.*, No. 17-cv-944-JFB-SRF, 2018 WL 3343238, at *2-3 (D. Del. May 11, 2018)). These Rule 12(c)-related motions should be denied for the additional reason that each of the defendants has failed to establish that it is entitled to the relief it seeks on the merits.

Here, where none of these defendants has established entitlement to the entry of judgment of non-infringement as a matter of law based solely on the pleadings, Plaintiffs respectfully urge the Court to follow its longstanding practice of not permitting dispositive motions in Hatch-Waxman cases—cases in which comprehensive post-trial briefing already will occur immediately after trial in any event. Unlike the *Amgen*, *Bendamustine*, and *Eagle* cases on which Defendants heavily rely, resolving these four motions in favor of Defendants will *not* end any one of the eighteen related matters. The Court will have to consider infringement of the '419 patent for each defendant in addition to validity and infringement of the four other patents-in-suit. Thus, these cases are going to proceed. And the parties have largely agreed to a schedule that provides

adequate time for fact and expert discovery related to the '419 patent. Moreover, Plaintiffs believe that the Court will benefit from a fully developed record, including fact and expert discovery on these important issues of infringement. *See Par Pharm., Inc. v. Hospira, Inc.*, No. 17-cv-944-JFB-SRF, D.I. 83, ¶7 (D. Del. Aug. 14, 2018) (“[Plaintiff] should also be given the opportunity to develop a full factual record”); *Lupin Atlantis Holdings v. Ranbaxy Labs., Ltd.*, No. 10-cv-3897, 2011 WL 1540199, at *3 (E.D. Pa. Apr. 21, 2011).

DEFENDANTS’ POSITION:

Plaintiffs have sued 18 defendant groups, asserting five patents alleged to cover products described in defendants’ ANDAs for brexpiprazole tablets. One of those patents, U.S. Patent No. 10,307,419 (“the ’419 patent”), is a formulation patent directed to pharmaceutical products that contain brexpiprazole and methods for manufacturing those compositions, while the other four patents (which are from the same family) are directed to the compound brexpiprazole and methods of using brexpiprazole to treat various conditions. The ’419 patent is the only patent for which the specific excipients in defendants’ formulations and in the prior art are relevant, and it has a different inventor from the other four patents. The ’419 patent expires over six years later than the other four patents.

As the Court has noted, four of the 18 defendants have already filed¹ motions seeking a judgment on the pleadings as to plaintiffs’ claim for infringement of the ’419 patent and many other defendants seek the Court’s guidance on how best to manage issues regarding noninfringement of this patent. Early resolution of defendants’ noninfringement claims

¹ Princeton (No. 19-1956, D.I. 15), Optimus (No. 19-2008, D.I. 12), Biophore (No. 19-1938, D.I. 12) (motion for leave to file a Rule 12(c) motion); and Hetero (No. 19-1954, D.I. 27), as those defendant groups are defined in the proposed Scheduling Order. All motions except the Hetero motion are fully briefed and ready for decision.

concerning the '419 patent could streamline fact and expert discovery, claim construction, and trial because the Court would no longer have to address infringement issues regarding the sole formulation patent as to many of the defendant groups. In the case of Apotex, the '419 patent is the only asserted patent, and its early resolution would dismiss the entire suit. For the rest of the defendants, dismissing the '419 patent would eliminate over six years of plaintiffs' potential exclusivity. Thus, although those cases would continue on the remaining patents, dismissal of the '419 patent would be significant.

In the four pending motions, defendants argue that their various ANDA products lack required claim elements and that infringement under the doctrine of equivalents is precluded based on, *inter alia*, the disclosure-dedication rule and/or prosecution history estoppel. Additional motions contemplated by other defendants would rely on at least the same legal principles. Indeed, the majority of the defendant groups assert similar noninfringement defenses concerning the '419 patent (e.g., lack of infringement due to disclosure-dedication). Accordingly, resolution of the pending 12(c) motions in defendants' favor will likely be dispositive of plaintiff's infringement allegations as to nearly all defendants. Whether there is sufficient time in the proposed Scheduling Order to complete discovery on the '419 patent is irrelevant. The key is that discovery is unnecessary and would be a waste of resources, and early resolution of the '419 patent will significantly impact the cases. Defendants refer to the existing 12(c) briefing for responses to the substantive issues raised by plaintiffs.

Invited by the Court's September 14th Order, defendants propose a potential course of action on how to proceed with these Rule 12(c) motions for the Court's consideration. Given the advanced stage of the currently pending motions, defendants request that the Court proceed with deciding these motions. The defendants who have not filed Rule 12(c) motions wish to avoid

delaying resolution of these motions and burdening the Court with additional Rule 12(c) motions directed to the same noninfringement issues at this time. However, those defendants would appreciate the Court's guidance as to when and how it would prefer to resolve similar non-infringement arguments. Of course, if the Court prefers to address these issues through additional Rule 12(c) motions, then the defendants who intend to file Rule 12(c) motions will certainly do so, according to the Court's preferred schedule—before the Court rules on the four currently pending motions, or after. In any event, defendants request the opportunity to participate in any hearing on the pending motions. With appropriate confidentiality provisions, these pending motions can be heard at the same hearing, to the extent the Court deems a hearing necessary.

II. Honour's Motion to Dismiss

PLAINTIFFS' POSITION:

Honour Lab Ltd. ("Honour") filed a motion pursuant to Fed. R. Civ. P. 12(b)(6) to dismiss Plaintiffs' Complaint against it, asserting that Honour is not the holder or submitter of the relevant ANDA. Plaintiffs respectfully request that the Court deny Honour's pending motion for the reasons presented in their brief (D.I. 18 in C.A. No. 19-1954-LPS).

III. Scheduling Order

A. Summary Judgment (Paragraph 16)

PLAINTIFFS' POSITION:

Plaintiffs oppose Defendants' proposal for summary judgment of non-infringement of the '419 patent. In December, when Defendants propose to exchange letter-briefs on the topic (Proposed Scheduling Order at ¶16), fact discovery will have barely begun, and the parties will be months away from the substantial completion of document production and a year away from the *start* of expert discovery.

Summary judgment on the bare record that will exist in December should not be permitted. *See Par Pharm.*, 2018 WL 3343238, at *3 (“[A]n infringement adjudication cannot be completed merely by reviewing the ANDA, and without taking into account any other evidence—including, most notably, expert testimony.”) (quoting *Lupin*, 2011 WL 1540199, at *3); *Par Pharm.*, No. 17-cv-944-JFB-SRF, D.I. 83 at ¶7.

Nor should summary judgment be permitted after fact and expert discovery have occurred. By that time, the cases will be close to trial, and hearing summary judgment motions would unnecessarily waste the Court’s and parties’ resources, particularly given the post-trial briefing that will occur. For at least these reasons, Plaintiffs respectfully request that the Court follow its typical practice disfavoring dispositive motions in Hatch-Waxman cases.

DEFENDANTS’ POSITION:

One of the few disputed aspects of the proposed Scheduling Order is that defendants request permission to file letter briefs seeking leave to file motions for summary judgment of noninfringement of the ’419 patent after plaintiffs serve infringement contentions. (*See* ¶ 16.) If the Court prefers not to resolve noninfringement of the ’419 patent on Rule 12(c) motions, Defendants request that they at least be allowed to request permission to file early motions for summary judgment regarding noninfringement of the ’419 patent. Defendants’ proposed schedule for summary judgment makes sense because it is after plaintiffs present their infringement contentions but before wasteful discovery that is unnecessary as a matter of law.

B. Sur-reply Expert Reports (Paragraph 9(j))

PLAINTIFFS’ POSITION:

A defendant’s obviousness challenge must address objective indicia of non-obviousness. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1076-80

(Fed. Cir. 2012). In practice, plaintiffs—and not defendants—put forth objective evidence of nonobviousness, and typically they do so for the first time in a rebuttal expert report. That is what the parties contemplate here. Proposed Scheduling Order at ¶9(j). Without the sur-reply that Plaintiffs propose, this important issue will be limited to only two rounds of expert reports, whereas the remaining issues benefit from three. Plaintiffs thus urge this Court to permit a sur-reply expert report on this topic consistent with other scheduling orders entered in this district. *E.g., Biogen Int'l GmbH v. Amneal Pharms. LLC*, No. 17-cv-823-LPS, D.I. 22 Scheduling Order, 13-14 (D. Del. Feb. 2, 2018) (“Sur-reply reports on validity that will be limited to Plaintiffs’ response to objective evidence of nonobviousness raised in Defendants’ reply expert reports on validity are due on or before July 25, 2019.”); *Cornell Univ. v. Illumina, Inc.*, No. 10-cv-433-LPS-MPT, D.I. 267 Joint Stipulation and Order to Amend the Scheduling Order and Amend the Complaint, 3-4 (D. Del. Mar. 23, 2015); *AbbVie Inc. v. Hetero USA Inc.*, No. 13-cv-852-RGA, D.I. 55, Scheduling Order, 7 (D. Del. June 30, 2014) (“Sur-reply expert reports by Plaintiffs, limited to expert opinions contradicting or rebutting the Defendants’ expert opinions relating to secondary considerations of non-obviousness, are due on or before April 27, 2015.”); *Forest Labs., LLC v. Sigmapharm Labs., LLC*, No. 14-cv-1119-SLR, D.I. 21 Scheduling Order, 6-7 (D. Del. Feb. 3, 2015) (“Plaintiffs may file Sur-reply reports on secondary consideration arguments raised for the first time in Defendants’ Supplemental reports by April 28, 2016.”).

DEFENDANTS’ POSITION:

Defendants propose that invalidity be treated like any other issue, with three rounds of expert reports, and the party with the burden on the issue serving the third and final report. Plaintiffs’ possible raising of secondary considerations in an invalidity rebuttal report does not change plaintiffs’ or defendants’ respective overall burdens with respect to invalidity. Secondary

considerations is part of invalidity due to obviousness, an issue on which defendants bear the overall burden. Plaintiffs' logic could equally be provided to grant defendants a sur-reply noninfringement report, something they do not seek. For example, defendants may raise issues of prosecution history estoppel for the first time in a noninfringement rebuttal report. Defendants do not then get a sur-reply report on prosecution history estoppel. Likewise, Plaintiffs should not be permitted to serve a sur-reply invalidity report.

C. Translations of Rule 33(d) Documents (Paragraph 9(g)(iii))

PLAINTIFFS' POSITION:

Plaintiffs oppose Defendants' blanket requirement to provide certified English translations of every foreign-language document a party cites in responding to an interrogatory. Defendants' proposal is procedurally premature. Cases in this Court and others that have addressed translations of Rule 33(d) documents do so in the context of motions to compel *after* the responding party has identified non-English language documents and the parties disagreed about whether English translations were required and, if so, who should pay for them. Rather than automatically saddle Plaintiffs with a significant burden to which they likely would be disproportionately subjected, Plaintiffs respectfully request that the Court instead allow the parties to work out any translation issues that may arise on a case-by-case basis.

DEFENDANTS' POSITION:

Defendants propose that a party citing a foreign-language document in response to an interrogatory be required to provide a certified translation. The inventors are Japanese, and, thus, documents cited in response to interrogatories are likely to be in Japanese. Should plaintiffs choose to take advantage of Rule 33(d), in whole or in part, rather than providing a fully self-contained substantive written response in English, then plaintiffs should be required to translate the documents. *See Invensas Corp. v. Renesas Elecs. Corp.*, C.A. No. 11-448-GMS-CJB, 2013 U.S.

Dist. LEXIS 199894, at *16-17 (D. Del. May 8, 2013) (granting motion to compel translations of documents produced under Fed. R. Civ. P. 33(d), noting that “there is a clear difference between a party moving to compel translation of foreign-language documents simply produced in response to requests for those specific documents, and . . . a party moving to compel translation of foreign-language documents produced in response to interrogatories, where such production is an alternative ‘option’ to answering the questions under the dictates of Rule 33(d)”). Defendants’ proposal is consistent with L.R. 7.1.3(d), which provides that when a party relies on foreign-language evidence, that party must provide a certified English translation of that foreign-language evidence.

D. Fact Depositions (Paragraph 9(h))

PLAINTIFFS’ POSITION:

Plaintiffs respectfully request that the Court adopt Plaintiffs’ position regarding fact depositions as set forth in the Proposed Scheduling Order at Paragraph 9(h). Plaintiffs believe that regardless of whether the depositions of Plaintiffs’ fact witnesses proceed in a foreign language, 100 total hours of deposition time and 12 total depositions should be more than sufficient for Defendants to develop their case. Defendants’ proposal is unreasonably burdensome.

DEFENDANTS’ POSITION:

With respect to fact depositions, the parties agree that there should be an overall fact-deposition hour limit for each side. The parties also agree that, absent foreign-language interpretation, individual fact depositions should be limited to seven hours (non-inventors) and ten hours (inventors). The parties have the following intertwined areas of dispute: (1) whether defendants should be limited to 12 fact depositions; (2) how much extra time should be allotted for foreign language depositions that require an interpreter—twice the agreed individual-deposition limit or merely an extra four hours; and (3) whether defendants should be limited to

100 or 180 hours of fact deposition testimony and whether additional time for translation should count against that overall hours limit. Defendants will address these in turn.

(1) Limiting defendants to 12 fact depositions would permit defendants to depose the named inventors but *no* additional witnesses, such as financial or regulatory witnesses or any non-inventor 30(b)(6) witnesses. There are twelve named inventors (including the sole inventor named on the '419 patent). At this stage of the case, defendants cannot know how many other witnesses will have relevant information and which inventors Plaintiffs will call at trial. Moreover, the hours limitations (including the agreed-upon limitations on individual depositions) will ensure defendants do not depose an unreasonable number of witnesses or depose any witness for an unreasonable amount of time. In addition, the parties have agreed to provisions that do *not* limit the number of depositions that plaintiffs can take of each defendant. Plaintiffs' attempt to impose such a limitation on defendants only is one-sided and prejudicial.

(2) As for the issue regarding added translation time for individual foreign-language depositions, the inventors are all Japanese, and plaintiffs have not indicated that any inventor understands English or agrees to forgo interpretation of attorney questions or their answers such that the deposition can be conducted largely in English. As defendants' collective prior experience in Hatch-Waxman cases suggests, foreign-language-speaking inventors and/or the counsel representing them do not agree to forgo interpreters, and the involvement of check and official interpreters in a deposition at minimum doubles the length of the deposition because each question and answer requires repeating. Thus, defendants' proposal of double time for individual interpreted depositions is reasonable. *See* Transcript of Case Management Conference at 12-14, *Adverio Pharma GmbH v. MSN Labs. Private Ltd. et al.*, C.A. No. 18-073 (LPS) (D. Del. Jun. 28, 2018), D.I. 32 (permitting double time for foreign language depositions) (Exhibit 2); Transcript at

39:12-23, 55:17-56:3, *Teles AG Informationstechnologien v. Cisco Systems, Inc.*, C.A. No. 9-072-SLR, D.I. 139(D. Del. Nov. 12, 2009) (Stark, J.) (permitting twice the amount of deposition time for witnesses that required the use of a translator, including for an English-speaking-but-native-German-speaking witness) (Exhibit 3).

(3) With respect to the total hours allotment, and whether additional translation time counts toward that allotment, defendants propose 180 hours excluding added translation time, whereas plaintiffs propose 100 hours including added translation time. Once again, plaintiffs' proposal is insufficient, particularly in view of plaintiffs' other proposals. Plaintiffs propose that interpreted, inventor depositions last up to $10+4=14$ hours. Thus, even though there are twelve named Japanese inventors, plaintiffs would provide defendants with sufficient time for just over seven full-length interpreted inventor depositions—let alone any non-inventor depositions. Defendants' proposal is based on 120 hours for inventor depositions (12 inventors, 10 hours each) plus 60 hours for non-inventor 30(b)(6) witnesses and additional non-inventor witnesses. Defendants properly exclude added translation time, which is incurred based on the needs of the witness, not the taking party. Plaintiffs' proposal to count such added translation time provides the perverse incentive to have a bilingual witness testify in a foreign language in order to take up more time. Defendants' proposal encourages any bilingual witness to elect to be deposed as much as possible in English in order to reduce the total length of the deposition.

IV. New Complaints Related to U.S. Reissue Patent No. RE48,059

PLAINTIFFS' POSITION:

Plaintiffs asserted U.S. Patent No. 7,888,362 ("the '362 patent") in the above-referenced actions.² The USPTO reissued the '362 patent on June 23, 2020, as RE48,059 ("RE'059"). Claims

² The '362 patent was not asserted against Apotex (C.A. No. 19-cv-2006-LPS).

1-9 of the '362 patent and claims 1-9 of RE'059 are identical. New claims 10 and 11 are directed to subgenera of original claims 3 and 4, respectively. New claims 12-15 of RE'059 depend from original claims 7 and 9 and are directed to brexpiprazole or a salt thereof.

Otsuka has received Paragraph IV Notice Letters regarding RE'059 from multiple defendants. To date, Otsuka has filed new Complaints against the Alkem Defendant Group (20-1286-LPS), Accord Defendant Group (20-1287-LPS), Amneal Defendant Group (20-1297-LPS), Lupin Defendant Group (20-1296-LPS) and Unichem Defendant Group (20-1295-LPS). Plaintiffs expect there to be others. Plaintiffs respectfully request that the Court consolidate these new actions with the lead Civil Action No. 19-1938-LPS (Proposed Scheduling Order at ¶1) and that the consolidated cases proceed according to the parties' agreed-upon schedule.

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